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EXAMINER
TURNER, SHARON L

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/11/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/724,288	Applicant(s) SCHENK ET AL.	
	Examiner Sharon L. Turner	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,48,50,60 and 68-77* is/are pending in the application.

4a) Of the above claim(s) *1,48,60 and 68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50 and 69-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,48,50,60 and 68-77* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendment filed 9-12-02 has been entered into the record and has been fully considered. Claims 1, 48, 50, 60 and 68-77 are pending.

Sequence Requirements and Specification

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

In the amendment of 10-19-01, Figures 19 and 20 were amended to refer to SEQ ID NO's 1-41. However, there appear to be 42 sequences represented in the figures, and thus at least one sequence identifier is apparently lacking. Applicants should clarify the peptides and their representative SEQ ID NO's: as presented in Figures 19-20.

Drawings

3. The drawing of Figure 11 is objected to because the figure lacks an appropriate legend which indicates the peptide treatment groups as indicated and described in the figure and specification, see in particular pp. 62-63 and brief description of the drawings, p. 7. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Applicants may alternatively choose to amend the brief description of the drawings so that it clearly reflects the groups represented in the Figure. Such amendment would be considered an appropriate correction so as to obviate abandonment of the application.

Information Disclosure Statement

4. The information disclosure statement filed 9-10-01 contains particular references which fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because they lack a relevant public availability date. Those references have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Election/Restriction

5. Applicant's election of Group III, claims 50 and 69-77 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is noted that applicant's referral to Group II is considered to be a typographical error in light of applicant's reference to the elected claims of Group III.

6. Claims 1, 48, 60 and 68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Double Patenting

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894); In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Claims 50 and 69-77 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 91-100 of copending Application No. 09/979,701 and claims 50-59 of copending Application No's. 09724552, 09724273 and 09/724551. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The claims constitute statutory double patenting as the claims are in fact duplicates.

Claim Objections

9. Claim 70 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is unclear how the claim is intended to further limit the way the recited components are combined as the combining provides contacting. Applicant's should clarify the intended difference in scope of the in-dependent and dependent claim.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 50 and 69-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 50 recites the limitation "combining the antigen-associated biological entity". However, the preamble sets forth two elements "a biological entity" and "an antigen" which differs from the terminology used within the body of the claim. The claim further specifies that "the biological entity" is "physically associated" with "the antigen". However, there is no particular "physical association" as set forth. The physical association may thus constitute a multitude of structural and/or functional co-operative relationships. For example, the elements may be near or adjacent to each other as amyloid is associated within blood vessels or brain tissue. Alternatively, the antigen and biological entity may be covalently bound by or an intrinsic part of the entity. Additionally the monitoring or measuring step may require measurement of a single element regadless of association or may require measurement of a particular type of association. For example, one could measure antigen whether or not it is bound by the entity or alternatively the measurement may be required to be of the antigen only as it is physically associated with the entity, i.e., only when it is bound. Thus, it is unclear to the artisan what element or elements s are being "combined" and what element or elements are being "monitored". It appears that either the "antigen" or the "biological

entity" alone may be combined and measured or alternatively that some particular complex of both elements may be combined and measured. As the preamble terminology is inconsistent with the body and endpoint of the claim, the skilled artisan cannot readily discern the metes and bounds of those element(s) that are combined and those element(s) that are monitored or measured.

13. The preamble of claim 50 recites screening for activity in clearing a biological entity, yet the monitoring step is towards "antigen-associated biological entity" and the end-point of the assay is an indication of activity in clearing the antigen. Therefore, the method steps as claimed does not apparently achieve the goals recited within the preamble. Thus the claim is indefinite as to the steps or elements which achieve screening "for activity in clearing a biological entity" which is not directly provided or measured in the assay.

14. Claim 69 is indefinite as set forth above. In particular, claim 69 recites monitoring the amount of the antigen remaining in the medium. Yet claim 50 only provides for the "antigen-associated biological entity". Applicants should clarify the monitoring step as to what is being monitored or measured.

15. Claims 73, 74 and 77 recite the limitation "the tissue sample" in reference to claims 50, 73 and 50, respectively. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

17. Claims 50, 69-72 and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Jorbeck et al., Infection & Immunity, 32(2):497-502, May 1981.

Jorbeck et al., tech the analysis of the specificity and activity of antibodies generated against different *Salmonella* antigens. The analysis is via in vivo and in vitro

phagocytosis assays measuring the ability of activated peritoneal exudates cells (PEC) to phagocytose and control of the growth of Salmonella in the presence of, see in particular abstract and p. 497, paragraph spanning columns 1-2. The in vivo and in vitro phagocytosis assays are described at p. 498 columns 1-2. The in vitro assays involve combination of PEC exudates containing polymorphonuclear leukocytes, lymphocytes and monocytes-macrophages (phagocytic cells bearing Fc receptors), with pre- or post-vaccination serum (containing antibodies), *Salmonella* (antigen/biological entity) and monitoring clearance of Salmonella bacteria via phagocytosis (antigen/biological entity). In the in vivo assays, particular mice were pre immunized with the various antiserum (antibodies), see in particular p. 498, column 1, Administration of rabbit antiserum to mice. The phagocytosis and clearance were measured by injeciton of Salmonella bacteria into central tail vein (biological entity) of mice followed by isolation of blood from the animal. For each bacterial strain and immunogen, the mean colony forming units in the blood from mice were expressed to calculate bacterial clearance (expressed as a percentage of bacterial counts/time). The results of the various antibodies in effecting clearance in vitro and in vivo are shown at pp. 498-502, Figures 2-3 and Tables 1-4. Thus, the in vivo analysis is in tissue, specifically blood tissue and the blood comprises inflammatory cells. Thus the reference teachings anticipate the claimed invention wherein the antigen is the biological entity (Salmonella bacteria) and wherein the antigen is in physical association with the biological entity, i.e., it is a part of the bacteria (biological entity).

18. Claims 50, and 69-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Vitek et al., US Patent No. 5,935,927.

Vitek et al., teach compositions and methods for stimulating amyloid removal in amyloidogenic diseases using advanced glycosylation endproducts. In particular the method includes stimulating mechanisms of recognition and removal of AGE-amyloid in an animal to remove the amyloid plaques via scavenger systems such as phagocytic cells, macrophages and in neural tissue microglial cells, see in particular column 6, line 36-column 7, line 33. A particular embodiment of the invention includes wherein the therapeutic agents include antibodies to AGE-amyloid, in particular antibodies to AGE-beta amyloid, see in particular column 7, lines 11-16, column 12, lines 46-67, column 15, column 16, lines 44-52. In addition, Vitek teaches where the effectiveness of an AGE bearing targeting agent can be tested for efficacy, see in particular column 21-22, paragraph spanning and column 24, lines 13-25, including the use of in vitro and in vivo assays, see in particular column 22, line 54-column 23, line 14. In particular assays the method provides for combination of anti-AGE antibody, various antigens including beta amyloid antigen and culture with phagocytic cells, including microglia with monitoring of the amount of AGE modified protein/antigen/biological entity amongst samples and over time. Similar in vivo assays are also contemplated as disclosed at columns 23-24. Thus, the assays may be in vitro or in biological tissue, particularly where the tissue is from the brain of an animal having amyloid plaques or Alzheimer's pathology. In the Vitek assays the antigen AGE, for example is a physical modification of beta amyloid and may or may not be present on the beta amyloid biological entity. Nevertheless, Vitek contemplates where the antigen is either present or absent from beta amyloid (the biological entity) and thus Vitek's teachings would encompass either interpretation of whether or not both antigen and entity are required to be in contact with antibody and phagocytic cells. The assays for monitoring the effectiveness in clearance would yield information pertaining to the different antibody agents used for treatment or clearance of

plaques and thus the assays necessarily recognizes the ability to distinguish the activity of particular agents (antibodies) in mediating AGE, amyloid or AGE plaque clearance. Animal tissue comprises inflammatory cells and Alzheimer's plaques are considered nonmalignant abnormal cell growth. Thus, the reference teachings anticipate the claimed invention regardless of the variable interpretations of an "antigen-associated biological entity" as set forth above.

Status of Claims

19. No claims are allowed.

20. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
December 10, 2002